

**REMARKS**

**I. STATUS OF CLAIMS**

Claims 1-43 are pending following entry of the amendments presented herein. Claims 1, 25, 28, 38, and 39 are amended herein. Support for the amendments to claims 1, 38, and 39 can at least be found in the present specification at paragraph [063]. Amendments to claims 25 and 28 correct dependency issues based on the amendment to independent claim 1. Accordingly, no new matter is added by the amendments presented herein.

**II. EXAMINER INTERVIEW**

Applicants wish to thank Examiner Paden for the curiosities extend to Applicants' undersigned attorney at the Examiner Interview on June 6, 2007. Applicants are in agreement with the statements regarding the substance of interview as presented in Examiner's June 6, 2007, Interview Summary.

**III. REJECTION UNDER 35 U.S.C. § 103**

The Office rejected claims 1-24 and 32-43 under 35 U.S.C. § 103(a) as unpatentable over WO 00/45648 to Zawistowski ("Zawistowski"). Office Action at page 2. In response to Applicants arguments, the Office contends that there is no difference seen between the homogenization of Zawistowski and the homogenization recited in the pending claims. *Id.* Applicants continue to respectfully disagree for the reasons of record and additionally, for the reasons provided below.

In order to establish a *prima facie* case of obviousness, the cited reference must teach or suggest all the elements of the claim. M.P.E.P. § 2143. Here, Zawistowski fails to teach or suggest all the elements of the present invention.

Specifically, the Office relies upon Example 1 of Zawistowski to teach the “mixing” and “homogenizing” steps of the present invention. Office Action at page 3, ll. 1-4. However, all of Zawistowski’s beverage examples are directed to milk-based or soy-based products. Zawistowski at Examples 1 and 5. Moreover, Zawistowski’s broad disclosure that his invention “may be used without further modification or adaptation and incorporated directly into foods, beverages . . .” fails to describe the presently claimed invention, especially considering that the examples are all drawn to milk or soy-based beverages.

As amended, the present invention is directed to a fruit juice containing aqueous material. Fruit juice containing aqueous material and milk/soy based aqueous material are known in the art to have different characteristics (*e.g.*, pH, natural components, etc.). As such, Zawistowski is deficient in teaching all the elements of the present invention. For that reason alone, Zawistowski fails to establish a *prima facie* case of obviousness.

Moreover, Applicants further submit that due to the large amount of protein (in comparison with fruit juice containing aqueous material) either added to or natively found in milk and soy-based beverages, the protein acts as a manufacturing aid to coat the plant sterol present, enabling its dispersion/solubilization in an aqueous vehicle. In fact, it was known in the art that protein added to and naturally found in aqueous

vehicles “coats” plant sterols for the dispersion contrary to sterols poor solubility in water.

For example, WO 00/41491 to Vulfson et al. (“Vulfson”) (previously submitted with the Information Disclosure Statement filed Feb. 9, 2004) explains that plant sterols in combination with a food additive allow for the inclusion of sterols in a food product or beverage. Vulfson at page 19. According to Vulfson, food additives encompass polypeptides such as milk-derived or soy-derived protein, polysaccharides such as modified cellulose, pectins and starch, or low molecular weight substances. *Id.* at pages 19 and 20. Those food additives form a coat “on the surface of sterol particles [that] can be directly observed by confocal laser microscopy when protein, for example, are labeled with an appropriate fluorescent . . . .” *Id.* at page 26. “A desirable property of the resulting coated composition is an ability to easily form an aqueous suspension.” *Id.* at page 27.

From the cited reference, Example 1 of Zawistowski mixes sterols/stanols with non-fat milk powder and 6L of liquid milk. Zawistowski at Example 1. Likewise, Example 5 of Zawistowski utilizes soy to prepare a soy drink. *Id.* at Example 5. Milk powder, milk and soy contain either natural or by addition milk-derived and/or soy-derived protein, as evidence by Vulfson. To that end, the protein contained in Zawistowski’s mixtures “coats” the sterols/stanols allowing for their inclusion into aqueous-food or beverage products.

Furthermore, the present invention, by proviso, excludes the use of “emulsifiers, thickening agents and/or *manufacturing aids* to achieve the substantially stable dispersion of the at least one hydrophobic plant sterol in said aqueous material.” *See,*

*e.g.*, claim 1 (emphasis added). The specification even provides that “the dispersion does not contain any added emulsifiers and thickening agents and other so-called ‘manufacturing aids,’ used in the food arts, *e.g.*, *encapsulation materials*.” Applicants’ Specification at page 11 (emphasis added). As further stated in Applicants’ specification, “manufacturing aids” include, *e.g.*, encapsulation aids, starches and pectin. *Id.* at page 15. Vulfson teaches that starches and pectin are polysaccharides that make-up possible food additives. Since Vulfson teaches that proteins “coat” the sterols analogously to the starches and pectin, protein can be considered an encapsulation aid. As such, the teachings in Zawistowski, *i.e.*, the use of milk or soy-derived food additives, are expressly excluded by the present invention and thus, cannot establish a *prima facie* case of obviousness.

Arguably, the fruit juice containing aqueous material of the present invention may include some amount of protein, and thus, the present invention, like Zawistowski, may comprise protein that could be coating the sterols to aid with dispersion. However, as provided below, the fruit juice containing aqueous material includes a distinctly different level of protein than milk or soy-based materials.

<b>Milk (1 cup)</b>	<b>Protein (g)</b>
Milk, reduced fat (2 percent)	8.13
Milk, low fat (1 percent)	8.03
Milk, non-fat (skim)	8.35
Milk, evaporated, non fat, canned	19.33
Milk, evaporated, condensed	24.2
Milk, buttermilk	8.11

Milk, chocolate, regular	7.93
Milk, soy	6.74

<b>Fruit Juice (1 cup)</b>	<b>Protein (g)</b>
Apple juice, unsweetened	0.15
Grape juice	1.42
Grapefruit juice	1.28
Orange juice	1.47
Pineapple juice	0.8
Prune juice	1.56
Tangerine juice, sweetened	1.25

From [http://www.annecollins.com/protein\\_diet/protein-milk.htm](http://www.annecollins.com/protein_diet/protein-milk.htm).

Despite fruit juice containing aqueous material including some protein, in comparison with milk or soy-based products, the milk or soy-based products contain at least about **four times** as much protein and in some instances, at least **fifteen times** as much protein depending on the milk product and fruit juice. As such, the protein attributed to the fruit juice does not rise to even the minimal level found in traditional milk-based products. Moreover, Vulfson not only explains that milk itself can contain those “food additives” for coating the sterols, but also teaches that the food additives do not have to come from the milk itself and instead, can be added to the plant sterols first and then, added to the milk. Vulfson at pages 12, 19, 20, and 22. By doing so, those food additives contribute even more protein to such a milk-based aqueous product. Since the protein found in the fruit juice containing aqueous material does not rise to the

level found in the milk or soy-derived products, this is just further evidence that the milk based and fruit juice based aqueous material are different.

For at least those additional reasons, a *prima facie* case of obviousness has not been established and Applicants respectfully request the withdrawal of this rejection.

#### IV. CONCLUSION


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 11, 2007

By:   
Adriana L. Burgy  
Reg. No. 48,564